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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/779,095	02/08/2001	Jean-Louis Gueret	20982-13	1674

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EXAMINER

JOYNES, ROBERT M

ART UNIT

PAPER NUMBER

1615

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DATE MAILED: 01/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/779,095

Applicant(s)

GUERET, JEAN-LOUIS

Examiner

Robert M. Joynes

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of applicant's Priority Papers and Information

Disclosure Statement filed on February 8, 2001.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31-34 provide for the use of a composite structure, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 31-34 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1- 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1, 10 and 27, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 4 and 10 recite that the optional filler is one or more *substantially inert* compounds. It is unclear what defining the filler compounds as substantially inert means.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 8 recites the broad recitation of the adhesive matrix containing 0.2% to 60% by weight of a moisture-absorbing compound, and the claim also recites a range of preferably 0.5% to 40% which is the narrower statement of the range/limitation. Claim 10 recites the broad recitation of the adhesive matrix containing one or more substantially inert compounds, and the claim

also recites that the inert compound is, in particular, the polyamide powder known the name Orgasol, which is the narrower statement of the range/limitation.

Claim 10 contains the trade name Orgasol to describe a particular polyamide powder. "If the trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of the 35 U.S.C. 112, second paragraph. *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used to properly identify any particular material or product." MPEP 2173.05 (u).

Claim 11 recites two indefinite terms. First, claim 11 recites healing agents. It is unclear what is meant by healing agents and what agents are thought to be healing agents. Second, Claims 11 recites nourishing agents. Again, it is unclear what is meant by nourishing agents and what agents are thought to be nourishing agents.

Claims 9, 11 and 14 are unclear because both claims are in improper Markush format because it is unclear whether the group is closed to any other agent or if the group was intended to remain open. The proper Markush format is the expression "selected from the group *consisting of*" and the use of the terms "and" OR "or" only before the last Markush member. It is suggested that applicant amend the claims by following the proper format so as to eliminate any uncertainty regarding the nature of the group.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5-9, 11 and 14 -18 are rejected under 35 U.S.C. 102(b) as being anticipated by Gueret et al. (US 5026552, hereafter "Gueret"). Gueret teaches a patch or mask comprising mesh support structure (Col. 3, lines 5-23), a gel containing an active agent (Col. 3, lines 24-66) and a support sheet (Col. 5, lines 26-37; Col. 8, lines 13-23)(Anticipating Claims 1, 15-18) wherein the support sheet can be permeable or impermeable (Col. 4, lines 41-57). The gel is formed from a water-soluble or water expandable polymer present in amounts between 0.5% and 50% by weight (Col. 3, lines 24-36)(Anticipating Claims 2, 5, 7, 8, 9). Those polymers include polyvinyl alcohol, alkaline metal salts of polyacrylic acid, alginates, starch polymers and polyacrylamide (Col. 3, lines 24-36)(Anticipating Claims 8, 9, 14).

The active agents are water-soluble and include silica, moisturizing agents, thinners, anti-wrinkle agents, stimulants, revitalizers, firming agents, and softeners (Col. 3, lines 52-66)(Anticipating Claims 6, 11

Therefore, Claims 1, 2, 5-9, 11, 14, 15 and 18 are anticipated by the Gueret reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, 5-9, 11, 14, 15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gueret. The teachings of Gueret are discussed above.

Gueret does not disclose the exact range for the amount of polymer present in the composition. Gueret teaches a range of 0.5% to 50% by weight of polymer in the gel component. The instant claims recite a range of 0.2% to 60%.

While the reference does not teach the complete concentration range, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to vary the amount of polymer present in the gel component of the composition.

One of ordinary skill in the art would have been motivated to do this prepare various compositions with differing amounts of the active agents or differing dosage levels wherein the amounts of the other ingredients would have to be adjusted.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 3, 4, 10, 19-30 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gueret in view of Peterson (US 5585111). The teachings of Gueret are discussed above. Gueret does not expressly teach the use of multiple layers of gel in the composition. Gueret does teach that different active agents can be incorporated into the gel and mesh composition and disposed of on the same support sheet (Col. 4, lines 54-57; Col. 7, lines 15-20).

Peterson teaches a patch composition comprising multiple layers of adhesive matrices that includes active agents in each matrix with a membrane between the first and second adhesive layers (Col. 2, line 17 – Col. 3, line 23; Col. 6, lines 20-51; Col. 13, Examples 23-28). The adhesive matrices are composed of methacrylic and acrylic copolymers (Col. 2, line 17 – Col. 3, line 23). The device is prepared in two portions and laminated together to form the multi-layer patch (Col. 6, lines 20-51).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a patch system that has multiple layers of adhesive matrices containing active agents.

One of ordinary skill in the art would have been motivated to do this to deliver multiple active agents to a patient or to extend or delay the release of the active agents.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 3, 4 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gueret in view of Lee et al. (US 4781924, hereafter "Lee"). The teachings of Gueret are discussed above. Gueret does not expressly teach the incorporation of inert fillers in the adhesive matrix.

Lee teaches that matrices of transdermal delivery devices can contain conventional components including dyes, pigments, permeation enhancers, excipients and *inert fillers* (Col. 9, lines 35-43). Lee teaches a transdermal device that includes a drug reservoir in the form of a matrix wherein different drugs can be contained within the matrix (Col. 5, lines 16-64).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare an adhesive matrix layer for a transdermal device that includes conventional components, specifically inert fillers.

One of ordinary skill in the art would have been motivated to do this to prepare a matrix with enhanced feel or to thicken the matrix or to aid in the binding or gelling of the matrix.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gueret in view of Jehan (GB 2307862). Gueret does not expressly teach the use of magnetizable particles in the composition.

Jehan teaches the incorporation of magnetizable particles in a transdermal patch composition (Page 2). In one embodiment, copper and zinc are the particulate incorporated and when placed on the skin small electromagnetic impulses are generated (Page 3-4).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to incorporate magnetizable particles into a transdermal patch composition.

One of ordinary skill in the art would have been motivated to do this treat skeletal or muscular pain (Page 4 of Jehan).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.


Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Monday through Friday 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes
Patent Examiner
Art Unit 1615
January 14, 2002


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